EXHIBIT F

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Dear Mr. Shaheen:

Representative Edward Gaffney has been kind enough to share with me your letter to him regarding lindane. I have also been made aware of a coalition that has been aggressively encouraging healthcare providers, such as yourself, to endorse a bill to ban lindane medications in the state of Michigan and make it a criminal felony to prescribe these medications—meaning put doctors in jail—regardless of the clinical situation. Unfortunately, much of the information that has been disseminated by these groups in support of the bill is misleading, obsolete, presented out of context or just plain inaccurate. This is a regretful situation and one that may negatively impact public health should this bill come to pass.

For example, you state (and I assume this information comes from one of several lindane "fact sheets" circulated by these special interest groups), that "about 20% of children with adverse side effects used the drug correctly." This statement is false. First of all, ALL medications are associated with side effects, even with proper use. The fact is that tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported. From 1951 and through 2002 only 488 adverse events were reported to the FDA through their Adverse Event Reporting System (AERS database).[1] The great majority of these events, 85%, were non-serious, and serious events most often resulted from product misuse—80% of cases (note that in 2003, lindane medications were limited to small, single-use, 2 oz. bottles to minimize this risk). This translates to 14 serious case reports to the FDA that occurred with proper drug use over a 51 year period of time, which is rare as noted in the FDA-approved lindane prescription label.

The safety of lindane is further supported by the results of a postmarketing surveillance study of over 34,000 patients that showed no difference between lindane and permethrin-based medications in terms of the number of serious adverse events reported.[2] In this study, the overall rate of side effects was exceptionally low for both treatments, at <0.5% each.
To date, Morton Grove Pharmaceuticals has received just 22 adverse event reports in the 10 years since we acquired the product. Again, the vast majority of these reports are non-serious,

including lack of efficacy and local skin reactions. In striking contrast, and to provide additional perspective, acetaminophen (Tylenol®) is known to cause 500 deaths and over 50,000 emergency room admissions annually, yet no one suggests banning this popular over-the-counter medication.[3]

You also state that "The US EPA considers it [lindane] a 'possible carcinogen'." This claim is also false. While this was the case prior to 1993, in 2001, the EPA downgraded lindane to having "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans."[4] This downgrade was based on an in-depth analysis of existing study data and new study data requested by the EPA after determining earlier studies to be inadequate. This is the same low carcinogenic rating that the EPA has determined for malathion (Ovide®) and permethrin (Nix® and Rid®)—two commonly prescribed first-line medications.

To date, there has been no established link between lindane medications and cancer in humans despite over 50 years of clinical use. In 1997, leading researchers involved in an epidemiological study based on a 140,000+ patient database from one of the largest HMOs, Kaiser Permanente, with more than 21 years of patient follow up concluded that, "There is still no persuasive evidence from studies in humans that lindane, as ordinarily used clinically, is carcinogenic in humans."[5] The WHO similarly concluded in 2002 that "In the absence of genotoxicity and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that Lindane is not likely to pose a carcinogenic risk to humans."[6]

Similarly, you note that "One dose of lindane can contaminate six million gallons of water..." This claim has absolutely no real-world scientific basis. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had lindane levels that were above conservative levels considered safe.[7] The EPA sets Maximum Containment Levels (MCL) for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping lindane levels below the even more conservative 1991 MCL of 0.2 ppb.[7]

To strike home how preposterous the "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" that if 100% of prescribed lindane shampoo and lotion sold in the Albany area (based upon the proportional number of New York 2004 prescriptions) was instead poured

directly into Albany's drinking water supply, lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the MCL considered safe in 2003.

The EPA has similarly concluded in its most recent scientific evaluations of lindane that, "[T]he Agency does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies."[8]

Lindane shampoo and lindane lotion are approved by the Food and Drug Administration (FDA) as prescription medications for the "second-line" treatment of scabies and lice. These parasitic diseases not only affect children but also adolescents and adults, bringing suffering and social stigma to thousands of Michigan residents and hundreds of millions of people worldwide. As second-line medications, lindane shampoo and lotion are indicated only when "first-line" therapies, such as Nix® or Rid®, have failed or cannot be tolerated by patients. Given that resistance to these agents, most notably permethrin[9], has increased in recent years, the availability of second-line medications like lindane is essential. Banning them would further limit a physician's ability to prescribe for these diseases and leave many patients without reasonable alternative.

Both the FDA and the Environmental Protection Agency (EPA), after repeated and exhaustive reviews by medical and scientific subject matter experts, have concluded that currently approved uses of lindane medications do not pose a significant risk to public health or safety. Consistently, the FDA has maintained that the benefits of lindane, when used appropriately, outweigh potential risks; again, a factor in the use of ALL medications.[10,11] The FDA continues to support the use and manufacture of lindane medications as second-line therapies for patients who have no other options. The EPA has consistently concluded that lindane poses no significant threat to public health or the environment.[8,12] Additionally, the CDC, which helps to set practice standards for the medical community, includes lindane as a recommended regimen for the treatment of pubic (crab) lice and as an alternate regimen for the treatment of scabies in their *Sexually Transmitted Disease Treatment Guidelines*.[13]

While the proponents of this bill claim that lindane medications are not necessary for alleviating the effects of these infections, the overwhelming evidence from those regulatory and health authorities charged with making these assessments, and with protecting public health and the environment and guiding proper drug usage is decidedly to the contrary. Ultimately, it is the FDA, and not the legislature, that should have the power to decide whether a particular pharmaceutical product should or should not be on the market.

Mr. Shaheen, the groups that have seeded the lay and medical communities with falsehoods have done a great disservice to those individuals empowered to make a difference. We wholly stand behind the safety of our products and the health benefits that they provide. Our goal is to set the record straight so that informed decisions can be just that. Under separate attachment you will find some of the most egregious claims that have been advanced by proponents of the lindane bill—each has been addressed within the appropriate context and supported with medical and scientific facts. Additional information can be found at www.Lindane.com—an information website that has been independently reviewed by thought leaders with specific expertise in pediatric medicine, dermatology and toxicology.

Kind Regards,

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References:

1. U.S. Food and Drug Administration (FDA). Lindane Post Marketing Safety Review. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneaeredacted.pdf.

2. Andrews EB, Joseph MC, Magenheim MJ, et al. Postmarketing surveillance study of permethrin crème rinse. *Am J Public Health*. 1992;82:857-861.

3. AASLD. Acetaminophen use and liver injury. 2004. Available at: https://www.aasld.org/eweb/DynamicPage.aspx?webcode=FastFacts_Acetaminop

4. U.S. Environmental Protection Agency (EPA). Evaluation of the Carcinogenic Potential of Lindane, PC. Code: 009001. 2001. Available at: http://www.epa.gov/pesticides/reregistration/lindane/CARC_final_report.pdf.

5. Friedman GD. Lindane and cancer in humans: A false alarm? *Pharmacoepidemiol and Drug Saf.* 1997;6:129-134.

6. World Health Organization. Lindane in Drinking Water: Background Document for Development of WHO Guidelines for Drinking-Water Quality. 2004. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/ lindane.pdf.

7. U.S. Environmental Protection Agency (EPA). Announcement of completion of EPA's review of existing drinking water standards. *Federal Register*. 68(138): July 18, 2003.

8. U.S. Environmental Protection Agency (EPA). Lindane Reregistration Eligibility Decision (RED). 2002.

9. Jones KN, English JC III. Review of common therapeutic options in the United States for the treatment of pediculosis capitis. *Clin Inf Dis*. 2003; 36:1355-1361.

10. U.S. Food and Drug Administration (FDA). Lindane Assessment Memorandum. 2002. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanememoassessment.pdf

11. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm

12. U.S. Environmental Protection Agency (EPA). Revised Assessment of Risk from Use of Lindane for Treatment of Lice and Scabies. July 31, 2002. Available at: http://www.lindane.com/pdf/EPA-Revised_Assessment-2002-07-31.pdf.

13. U.S. Centers for Disease Control and Prevention (CDC). Ectoparasitic infections. Sexually transmitted diseases treatment guidelines 2002. *MMWR Recomm Rep* 2002 May 10;51(RR-6):67-69.

Below are responses to misleading claims as purported by special interest groups seeking to ban the use of FDA-approved prescription lindane medications in the United States

1. **CLAIM**: Proponents claim that "In the FDA's Adverse Event Reporting, 20% of those reporting health effects due to lindane used the product according to directions."

FACT: This statement is false. The fact is that tens of millions of prescriptions for lindane medications have been written in the 50+ years they have been on the U.S. market, yet relatively few adverse events have been reported. From 1951 and through 2002, only 488 adverse events were reported to the Food and Drug Administration (FDA) through their Adverse Event Reporting System (AERS database).[1] The great majority of these events, 85%, were non-serious, and serious events most often resulted from product misuse—80% of cases (note that in 2003, lindane medications were limited to small, single-use, 2 oz. bottles to minimize this risk). This translates to 14 serious case reports to the FDA that occurred with proper drug use over a 51 year period of time, which is rare as noted in the FDA-approved lindane prescription label. In the last 10 years, just 22 adverse events have been reported directly to the manufacturer, Morton Grove Pharmaceuticals, Inc. Again, the vast majority of these reports were non-serious, including lack of efficacy and local skin reactions.

In striking contrast and to put proponents' claims into proper perspective, acetaminophen (Tylenol®) is known to cause 500 deaths and over 50,000 emergency room admissions annually, yet no one suggests banning this popular over-the-counter product.[2]

In short, ALL medications are associated with side effects, even with proper use.

2. **CLAIM**: Proponents claim that "The risk for toxic effects is estimated to be 40-400 times lower for permethrin cream than lindane lotion."

FACT: This claim has no clinical basis and is not supported by studies in humans. In a large postmarketing safety trial involving more than 34,000 patients, there was no significant difference in the rate of serious adverse events reported for lindane and permethrin—a common first-line therapy.[3] Moreover, the overall rate of side effects reported for both treatments was exceptionally low, at less than 0.5% each. These findings are particularly meaningful given the large patient sampling and the real-world nature of postmarketing analyses (ie, safety under normal-use conditions). In addition, this study was conducted before lindane medications were limited to single-use, 2 oz. bottles. This important packaging

change, which was implemented in 2003, has dramatically reduced the risk for lindane misuse and further enhanced the safety profile of these medications.

The claim that permethrin is 40-400 times less toxic than lindane is not based on real-world use of these medications but rather data collected "in vitro" in a laboratory using guinea pigs.[4] It is a theoretical projection that is based on "overuse conditions" and not on how either treatment would normally be prescribed or used by patients. Even the authors of this study note that, "Unfortunately, published data to support this conclusion are limited."[4]

3. **CLAIM**: Proponents claim that "Lindane is readily absorbed into the body upon exposure, and causes acute toxicity to the nervous system."

FACT: ALL scabies and lice medications have the "potential" to cause toxicity to the nervous system because of how they work, including first-line agents that are not under consideration for ban or restriction. According to the World Health Organization (WHO)1998 Collaborating Centre for International Drug Monitoring, convulsions have also been associated with commonly used first-line medications, including malathion, permethrin and crotamiton.[5] When used properly, serious side effects with lindane medications are exceptionally rare (see claim #1).

4. **CLAIM**: Proponents claim that "Acute intoxication results in central nervous system symptoms such as numbness, motor restlessness, anxiety, tremors, cramps and unconsciousness that can evolve to coma or death within the first 24 hours after oral ingestion."

FACT: This statement is highly misleading. From 1951 through 2002, only 3 deaths confirmed to be related to lindane medications were reported through the FDA AERS database.[1,6] In each instance, these medications were misused (see claims #1 and #3). This is no different than other first-line treatments, such as permethrin, which have also been associated with serious drug reactions and death in extremely rare instances.[5]

The proponents' claim is taken from a scientific review article on pharmacotherapy of ectoparasitic infections by Roos TC, et al.[7] What proponents do not reveal is that the above effects related to gross misuse of lindane medications and were reported prior to 2003, when these medications were available in large 16 oz. containers and the potential for misuse was much greater than it is today. The authors of the referenced article provide context for the above statement by noting that, "In this situation, it has been emphasized that neurotoxic effects do not occur when the drug is used appropriately."[7] They also cite other research reports that draw similar conclusions. For example, Shacter B, et al. state that, "There is little

evidence that the preparations [lindane] used in the treatment of scabies and pediculosis give rise to toxic symptoms when applied according to directions."[8] Similarly, Rasmussen JE, et al. conclude after an "in-depth" review of lindane that, "Almost all of the suspected adverse drug reactions (ADR) from 1% lindane have involved substantial misuse."[9]

Moreover, results of a collaborative analysis by the Centers for Disease Control and Prevention (CDC), FDA, and Environmental Protection Agency (EPA) of unintentional lindane ingestions reported to authorities between 1998 and 2003 showed that even in a misuse situation, serious adverse reactions were uncommon.[10] The vast majority, 91%, of unintentional ingestions (870 in total) were associated with non-serious events, such as nausea and vomiting. Only 3% resulted in seizure, while none resulted in death. The change in lindane packaging to single-use bottles, implemented in 2003, has dramatically reduced the risk of misuse and accidental ingestion of large quantities of lindane.

The most common side effects associated with the proper use of lindane medications are non-serious reactions of the skin, including burning, itching, dryness and rash.[11,12]

5. **CLAIM**: Proponents claim that "Chronic oral exposure includes effects on the blood, immune, and nervous systems, and the liver and kidneys."

FACT: This claim is not based on findings in humans but rather the effects noted in animals fed lindane orally over prolonged periods of time.[13] It has no real-world applicability to the healthcare uses of lindane medications, which are applied topically to human skin and hair in small amounts and in low concentration, typically as one-time treatments.

6. **CLAIM**: Proponents claim that lindane is "classified as a possible carcinogen by the EPA."

FACT: While it is true that before 1993 the EPA classified lindane as a "possible / probable" carcinogen, in 2001 the EPA downgraded lindane to having "suggestive evidence of carcinogenicity, but not sufficient to assess cancer risk to humans."[14] This downgrade was based on an in-depth analysis of existing study data and new study data requested by the EPA after determining earlier studies to be inadequate. This is the same low carcinogenic rating that the EPA has determined for malathion (Ovide®) and permethrin (Nix® and Rid®)—two commonly prescribed first-line medications.[15,16]

To date, there has been no established link between lindane medications and cancer in humans, despite more than 50 years of clinical use. In 1997, leading researchers involved in an epidemiological study based on a 140,000+ patient database from one of the largest HMOs, Kaiser Permanente, with more than 21 years of patient follow up concluded that,

"There is still no persuasive evidence from studies in humans that lindane, as ordinarily used clinically, is carcinogenic in humans."[17] The WHO similarly concluded in 2002 that, "In the absence of genotoxicity and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that lindane is not likely to pose a carcinogenic risk to humans."[18]

7. **CLAIM**: Proponents claim "The use of pediculocidal shampoos (including lindane) was associated with an increased risk of childhood leukemia..."

FACT: This claim is inaccurate. It is based on a French study published in the journal *Occupational and Environmental Medicine*[19]; however, the results do not support an association between lindane shampoo and childhood leukemia. In fact, in this study, Only 6 children were treated with lindane. The vast majority of children (65 in total) were treated with commonly used over-the-counter pyrethroid-based shampoos like Nix® and Rid®. Moreover, when evaluating treatments separately, the association with lindane was not significant as reflected in a confidence interval that included the "no effect" value of 1.0.—ie, no association with lindane was established.

8. **CLAIM**: Proponents claim that "The availability of safe, more effective alternatives to lindane has virtually eliminated its use for lice treatment in the United States."

FACT: Despite the availability of newer scabies and lice medications, lindane lotion and shampoo have become anything but obsolete. In 2005, nearly 300,000 prescriptions were written for patients that required these medications. First-line scabies and lice medications, including prescription and over-the-counter products, are effective for many patients afflicted by these diseases. However, no treatment works all of the time and some patients are unable to tolerate first-line therapies because of adverse side effects, allergies or contraindications. Moreover, increasing rates of drug-resistant lice and scabies have been observed, most notably to permethrin[20,21]—the most commonly prescribed first-line treatment—which further underscores the need for multiple treatment options and second-line alternatives like lindane.

9. **CLAIM**: Proponents claim that "An FDA approved lice comb is an effective, non-chemical approach to treat lice infestation (example: LiceMeister Comb produced by the National Pediculosis Association)."

FACT: Aside from being extremely labor intensive and impractical, evidence for the effectiveness of combing in controlling lice infestations is generally lacking.[20] In a rigorous head-to-head clinical study published in the esteemed medical journal *Lancet*, manual

removal of head lice with a commercial combing kit was found to be less than half as effective as treatment with a prescription pediculicide.[22] Both the CDC and the American Academy of Pediatrics (AAP) designate pediculicidal medications as the preferred approach over manual removal with special combs for the treatment of head lice.[23,24]

Additionally, statements against the use of lindane medication in favor of nit combs must be closely scrutinized as these statements have been aggressively advanced by the National Pediculosis Association (NPA), a special interest group of non-healthcare professionals that directly profits from the sale of nit comb products.

10. **CLAIM**: Proponents claim that "Lindane resistance has been reported in the United States for both lice and scabies—this means that the organisms have become immune to the chemical."

FACT: Resistance is a concern for ALL available scabies and lice medications, even those more recently developed. It has not only been reported for lindane, but also for ALL first-line agents (eg, permethrin, pyrethrin, malathion).[26-32] The development of resistance is unpredictable and can vary geographically, thereby limiting the number of viable treatment options for a given individual or even populations of people living in a particular area or setting. Thus, while resistance diminishes a drug's efficacy, it does not render it ineffective for all patients. Of more recent concern is evidence that resistance of head lice to over-the-counter permethrin, the most commonly prescribed first-line treatment, has significantly increased[20,21]—meaning more patients will require second-line alternatives (see claim #11). Banning lindane medications would only further limit the ability of healthcare providers to prescribe for these patients.

11. **CLAIM**: Proponents claim that "Lindane is the least effective treatment for head lice and scabies..."

FACT: The fact is that a significant number of patients in the U.S. require lindane medications each year. This is supported by national prescription data and anecdotal reports from healthcare providers who continue to successfully use lindane medications in appropriately selected patients with scabies, public lice and head lice [Personal communications with Morton Grove Pharmaceuticals, Inc].

The above claim is based on the results of an "in vitro" study conducted in Florida.[33] Extrapolation of these findings to the rest of the country has no scientific basis given that resistance and thus efficacy of approved medications can vary "country to country and region to region within a country."[33] Moreover, other studies conducted in patients with scabies and

lice have demonstrated good "clinical cure rates" following treatment with lindane medications.[35-37]

12. **CLAIM**: Proponents claim that "Lindane poses an environmental threat because it is a persistent, bioaccumulative toxin."

FACT: Environmental exposure to lindane (gamma-hexachlorocyclohexane or gamma-HCH) through the use of lindane medications is insignificant. More than 99% of lindane use in the U.S. is for agricultural purposes.[38] Less than 1% is used in healthcare. In 2002, the EPA concluded that currently approved uses of lindane, both agricultural and medical, pose no significant threat to the environment or the public.[39,40] The CDC's Agency for Toxic Substances and Disease Registry (ATSDR), further states that, "gamma-HCH [lindane] is broken down into less harmful substances by algae, fungi, and bacteria in soil, sediments and water."[41]

13. **CLAIM**: Proponents claim that "One dose of lindane can contaminate six million gallons of water."

FACT: There is no real-world scientific basis for this claim. In 2003, the EPA published test results of 16,000 water systems serving 100 million people, and found that 0% had lindane levels that were above conservative levels considered safe.[42] The EPA sets Maximum Containment Levels (MCL) for many contaminants. The MCL is defined as the level at which no known or anticipated adverse health effects will occur. In 1991, the EPA set the MCL for lindane at 0.2 parts per billion (ppb). In 2003, in light of new data on the health effects of lindane, the EPA found it justified to raise the MCL to 1.0 ppb; however, the higher rate was not implemented because states had no apparent difficulty in keeping lindane levels below the even more conservative 1991 MCL of 0.2 ppb.[42]

To strike home how preposterous the "water contaminant claim" is, a study by Shayne C. Gad, Ph.D., adjunct Professor of Toxicology, Duke University Medical Center, concluded in a "worst-case scenario" analysis that if 100% of prescribed lindane shampoo and lotion sold in the Albany, New York area (based upon the proportional number of New York 2004 prescriptions) was instead poured directly into Albany's drinking water supply, lindane levels would still be 67-times lower than the conservative 1991 safety level for drinking and 333-times lower than the level considered safe in 2003.

The EPA has similarly concluded in its most recent scientific evaluations of lindane that, "[T]he Agency does not have risk concerns for concentrations of lindane in surface water used as a source of drinking water from consumer use for both lice and scabies."[39]

14. **CLAIM**: Proponents claim that lindane is an "organochlorine pesticide used for the control of lice and scabies in children and also used in agriculture as a seed treatment for barley, corn, oats, rye, sorghum, and wheat."

FACT: Lindane medications contain 1% highly purified pharmaceutical-grade gamma-HCH and are specifically developed for healthcare purposes and use in humans. They are FDA-approved for the treatment of head lice, pubic lice and scabies—diseases that affect not only children but adolescents and adults. Like all prescription medications, they are formulated to the standards of the United States Pharmacopeia (USP)—the official public authority that sets quality standards for drugs manufactured and sold in the U.S.[43] Lindane Lotion USP, 1% is pharmacologically classified as a scabicide. Lindane Shampoo USP, 1% is pharmacologically classified as a pediculicide. Lindane medications have never been used agriculturally as pesticides.

The active ingredient in lindane medications (gamma-HCH) is used in a different form for agricultural purposes. This is no different than the active ingredients in other first-line scabies and lice medications, such as Nix® (permethrin), Rid® (pyrethrin) and Ovide® (malathion), which are ALL used in agriculture and registered with the EPA as pesticides.[44-46] In contrast to pharmaceutical-grade lindane, "agricultural-grade" gamma-HCH (1) is not intended for human use, (2) has never been used in healthcare, (3) provides no public health benefit and (4) is not regulated by the FDA.

Additionally, many of the environmental and health claims made about lindane by those wishing to ban its use relate to occupational exposure of farm workers and individuals working in seed-treatment facilities to chronic and high concentrations of agricultural-grade lindane. In fact, many of the claims apply primarily or exclusively to other chemicals that have historically been used agriculturally in the U.S., namely the alpha and beta isomers of HCH and not the gamma form.

Alpha- and beta-HCH are chemically distinct and notably the more toxic isomers:[38,47]

- Alpha- and beta-HCH are the dominant forms found in the environment and the most common forms found in animal and human tissues and fluids
- Technical-grade HCH—a mixture of alpha-HCH (60-70%), beta-HCH (5-12%), and gamma-HCH (10-15%)—was used agriculturally in the U.S. until 1978 but is still used in other parts of the world; technical-grade HCH has never been used in medicine
- Unlike gamma-HCH (lindane), alpha- and beta-HCH have no insecticidal activity and provide no value to healthcare

15. **CLAIM**: ATSDR ranks lindane 32 of 275 in the list of CERLA priority pollutants due to its "toxicity, potential of exposure, and frequence of occurrence at National Priority Sites."

FACT: This claim is based on a list of "potentially" hazardous substances put together by the CDC's Agency for Toxic Substances and Disease Registry (ATSDR). Chlorine and ammonia are also included on this list.[48] It is important to point out that this list is not a list of most hazardous substances, but rather a list of substances that are monitored by this group based on a number of different factors. Highlighted in bold in the ATSDR report is the following statement: "It should be noted that this priority list is not a list of 'most toxic' substances, but rather a prioritization of substances based on a combination of their frequency, toxicity, and potential for human exposure at NPL sites" (NPL, or National Priority List, sites are industrial facilities that generate chemical waste).[48] Today, more than 99% of all lindane sold in the U.S. is used for agricultural purposes; less 1% is used in healthcare.[38]

16. **CLAIM**: Lindane was recently proposed as an addition to the Stockholm Convention list of "persistent organic pollutants targeted for global elimination."

FACT: Much of the world still uses lindane (gamma-HCH) widely in agriculture. Here in the U.S., the majority of registered agricultural uses were cancelled by the EPA years ago.[39] Similarly, technical-grade HCH—a more toxic HCH agricultural mixture composed predominately of alpha and beta isomers—has not been used in the U.S. since 1978 but continues to be used in other parts of the world.[38] Today, lindane is approved for use as a pre-planting seed treatment for six crops and pharmaceutically for the second-line management of scabies and lice. The FDA and the EPA have repeatedly rejected efforts to ban these products despite interest group pressures similar to those being brought in Michigan. Moreover, petitions to ban lindane medications, specifically, have been repeatedly determined to be without merit.[49] Consistent with all this, public reports of the congressional consideration of the Stockholm Convention reveal that Congress has no interest in overruling FDA and EPA views on lindane.

References:

1. U.S. Food and Drug Administration (FDA). Lindane Post Marketing Safety Review. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneaeredacted.pdf.

2. AASLD. Acetaminophen use and liver injury. 2004. Available at: https://www.aasld.org/eweb/DynamicPage.aspx?webcode=FastFacts_Acetaminop

3. Andrews EB, Joseph MC, Magenheim MJ, et al. Postmarketing surveillance study of permethrin crème rinse. *Am J Public Health*. 1992;82:857-861.

4. Franz TJ, Lehman PA, Franz SF, et al. Comparative percutaneous absorption of lindane and permethrin. *Arch Dermatol.* 1996:132:901-905.

5. Wendel K, Rompalo A. Scabies and pediculosis pubis: an update of treatment regimens and general review. *Clin Infect Dis.* 2002;35:S146-S151.

6. U.S. Food and Drug Administration (FDA). Public health advisory: Safety of topical lindane products for the treatment of scabies and lice. March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm.

7. Roos TC, Alam M, Roos S, et al. Pharmacotherapy of ectoparasitic infections. *Drugs.* 2001;61:1067-1088.

8. Shacter B. Treatment of scabies and pediculosis with lindane preparations: an evaluation. *J Am Acad Dermatol.* 1981;5:517-527.

9. Rasmussen JE. The problem of lindane. *J Am Acad Dermatol.* 1981;507-516.

10. U.S. Centers for Disease Control and Prevention (CDC). Unitentional topical lindane ingestions—United States, 1998-2003. *MMWR Weekly.* 2005;54:533-534.

11. Medication Guide Lindane Lotion USP, 1%. Updated March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneLotionGuide.htm.

12. Medication Guide Lindane Shampoo USP, 1%. Updated March 28, 2003. Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindaneShampooGuide.htm.

13. U.S. Environmental Protection Agency (EPA). Lindane Hazard Summary. Available at: http://www.epa.gov/ttn/atw/hlthef/lindane.html.

14. U.S. Environmental Protection Agency (EPA). Evaluation of the Carcinogenic Potential of Lindane, PC. Code: 009001. 2001. Available at: http://www.epa.gov/pesticides/reregistration/lindane/CARC_final_report.pdf.

15. U.S. Environmental Protection Agency (EPA). Evaluation of the Carcinogenic Potential of Malathion. 2000. Available at: http://www.epa.gov/pesticides/op/malathion/cancer.pdf

16. PAN Pesticides Database. Permethrin-identification, ecological toxicity and regulatory information. Available at: http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35397

17. Friedman GD. Lindane and cancer in humans: A false alarm? *Pharmacoepidemiol and Drug Saf.* 1997;6:129-134.

18. World Health Organization. Lindane in Drinking Water: Background Document for Development of WHO Guidelines for Drinking-Water Quality. 2004. Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/lindane.pdf.

19. Menegaux F, Baruchel A, Bertrand Y, et al. Household exposure to pesticides and risk of childhood acute leukemia. *Occup Eviron Med.* 2006;63:131-134.

20. Jones KN, English JC III. Review of common therapeutic options in the United States for the treatment of pediculosis capitis. *Clin Inf Dis.* 2003; 36:1355-1361.

21. Burkhart CG, Burkhart CN. Clinical evidence of lice resistance to over-the-counter products. *J Cutaneous Med Surg.* 2000;4:199-201.